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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,213	08/02/2005	Shyam B. Karki	21346P	1534
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 10/16/2007		EXAMINER WESTERBERG, NISSA M	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/544,213

Applicant(s)

KARKI ET AL.

Examiner

Nissa M. Westerberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2 sheets.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, powdered formulations in the reply filed on August 27, 2007 is acknowledged. The traversal is on the ground(s) that the inventions are related to the same compound and that a reasonable comprehensive search would result information on both powders and granules. This is not found to be persuasive. While all the groups contain the same chemical compound, 3-[5-(4-methanesulfonyl-piperazine-1-ylmethyl)-1H-indol-2-yl]-1H-quinolin-2-one, that is not the inventive feature. Whether art found during the search for a powdered formulation for use with a diluent (group I) would return art relevant to granulation for use with a diluent (group II) cannot be known until after the search is performed.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The use of the trademarks "Ora-Sweet", "Ora-Plus" and "Ora-Sweet SF" have been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1- 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraley et al: (US Patent 6,306,874) in view of Remington (Remington: The Science and Practice of Pharmacy, p 802 – 803).

Fraley et al. teaches compounds that are tyrosine kinase inhibitors, including 3-[5-(4-methanesulfonyl-piperazine-1-ylmethyl)-1H-indol-2-yl]-1H-quinolin-2-one, compound 5-10. Once synthesized, this compound is a bright yellow solid (col 75, ln 10 – 37). The compounds were tested and found to have kinase inhibitory activity (col 26 ln 66 – col 27, ln 1). Possible routes of administration of the inhibitors include intramuscular, intraperitoneal, subcutaneous and intravenous use with sterile solutions (col 20, ln 7 – 9).

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Remington teaches that products stored in the dry state after freeze-drying or lyophilization have few stability problems (p 802, col 1, paragraph 1). Components of a typical freeze dry formulation include excipients to increase the amount of solids present (p 803, col 1, paragraphs 3 – 4). Carbohydrates are one class of substances that can be used as excipients. Exemplified carbohydrates are dextrose, mannitol and dextran but other carbohydrates such as microcrystalline cellulose are also known excipients. Determining the amount of such ingredients in the composition would be a matter of routine optimization as the drying rate is affected by the amount of solids present (p 803, col 1, paragraph 1).

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In *re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05.**

Given the teachings of Remington as to general considerations and initial parameters, one of ordinary skill would have a reasonable expectation of success in formulating a powder composition of 3-[5-(4-methanesulfonyl-piperazine-1-ylmethyl)-1H-indol-2-yl]-1H-quinolin-2-one as taught by Fraley et al. as part of routine formulation work.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 – 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,656,942. Although

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the conflicting claims are not identical, they are not patentably distinct from each other, Claim 8 of '942 recites a pharmaceutical composition of the mesylate or chloride salt of 3-[5-(4-methanesulfonyl-piperazine-1-ylmethyl)-1H-indol-2-yl]-1H-quinolin-2-one with a pharmaceutically acceptable carrier and lactose is provided as an example (col 7, ln 23 – 27). One of ordinary skill in the art would have used the relevant 2-one compound with the necessary carrier ingredients to form a powder or granule to make the tablet or capsule form, resulting in the claimed subject matter of the instant application.

### ***Conclusion***


Claims 1 – 6 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571) 270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

  
CECIL A. TSING  
SUPERVISORY PATENT EXAMINER